USEPA's Registration and Reevaluation Process & Stakeholder Involvement

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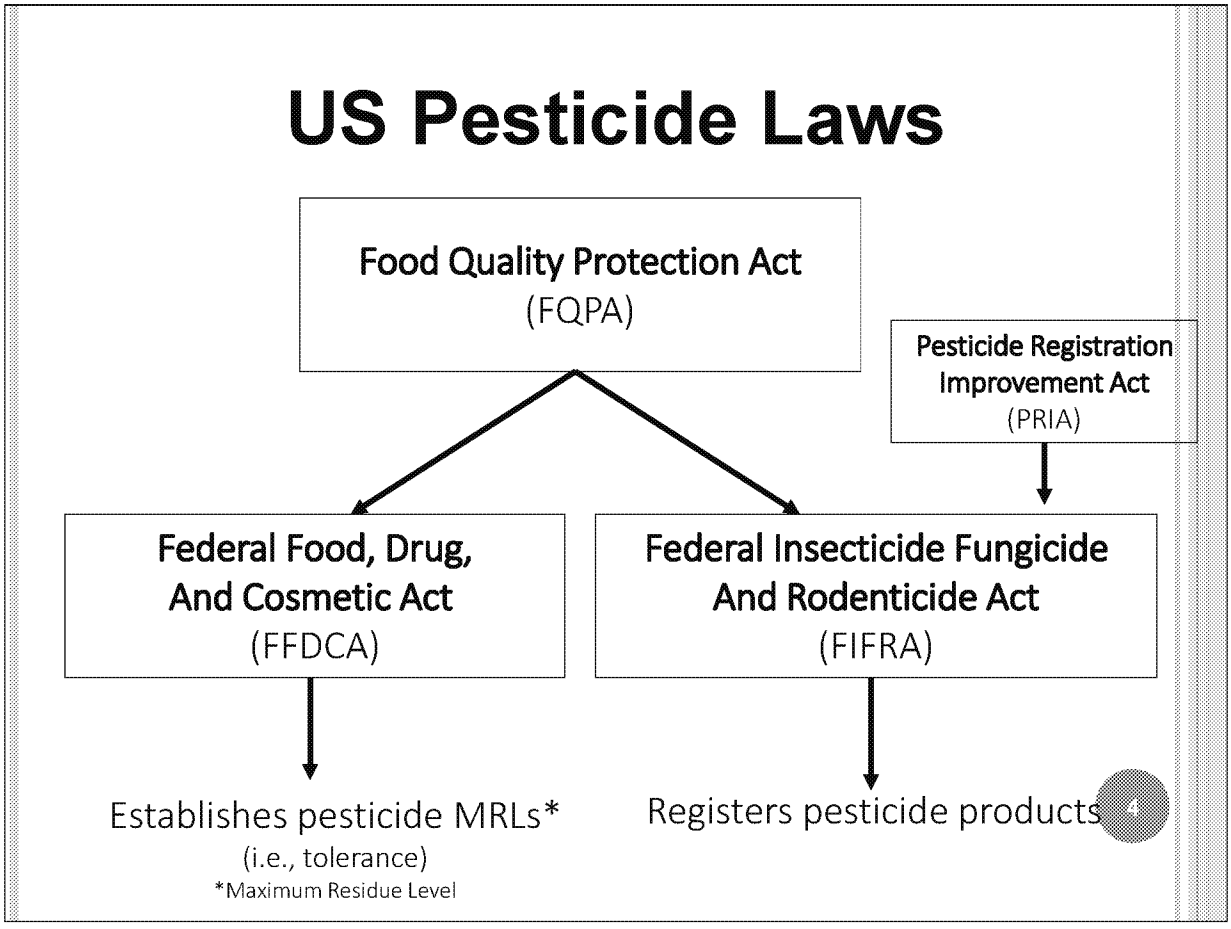
AGENDA TOPICS

- Statutes
- Registration
- Reevaluation
- Alternatives and Benefits
- Public Participation Process

STATUTES

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Federal Food, Drug, and Cosmetic Act (FFDCA)
- Food Quality Protection Act (FQPA)
- Pesticide Registration Improvement Act (PRIA)
- Endangered Species Act (ESA)

US Pesticide Laws



Pesticide Registration Improvement Act (PRIA)

- PRIA was last reauthorized in 2012
- PRIA was developed by a coalition of stakeholders including pesticide manufacturers, growers and public interest groups
  - EPA provides technical assistance to the PRIA Coalition, Congress, and OMB
- PRIA established a fee for service framework that charges applicants based on the activity requested, and holds the EPA to mandatory time frames for reviewing and making decisions on these actions
- The purpose of this registration fee system is to **provide additional resources to OPP in order to achieve more predictable and faster registration decisions**

Pesticide Registration Improvement Act (PRIA) Service Fees and Fee Waivers

- PRIA Registration Service Fees- FIFRA section 33
  - PRIA fees are one time registration service fees that support the evaluation of new applications submitted to the EPA
  - Currently 189 fee categories covering a broad array of activities

- PRIA provides fee waivers to small businesses:
  - 50% fee waiver for businesses with < 500 employees and ≤ $60M in global pesticides sales
  - 75% fee waiver for businesses with < 500 employees and ≤ $10M in global pesticide sales

- PRIA provides an exemption from fee requirements to federal/state agencies and to applications associated with IR-4 tolerance petitions (USDA program to fund the development of data to register pesticides on minor use crops)

Success of PRIA

- PRIA implementation has an excellent track record and has earned great support from stakeholders including registrants, public interest groups and Congress
- The pesticide industry and growers greatly value the increased predictability of EPA's decision-making that PRIA provides
- Registrants have actively sought to increase the number and kinds of registration actions covered under the fee for service program (90 categories covered under PRIA1, 140 categories under PRIA2 and 189 categories under PRIA3)

Pesticide Categories

- EPA separates pesticides into three general categories:

  1. Conventional Chemical Pesticides
  2. Antimicrobial Pesticides
  3. Biopesticides

- Depending on the type of pesticide under review, different Divisions of OPP will evaluate the action, and the data requirements for registration will vary.

OPP Registration Process: Risk Assessment & Risk Management

1. Registrant develops a pesticide, conducts studies, and submits a registration application.
2. OPP scientists review studies to assess the risk of a pesticide.
3. OPP risk managers make the decision whether to register a pesticide or change a registration based on the study reviews, benefits, and any adverse incident information.
4. Decision includes product labeling, packaging, and directions for use, and any limitations on where, how, and when a pesticide may be applied.

Each pesticide decision is unique although the approach is generally the same.

Types of Registration Applications

- New Active Ingredient Registration
- New Product Registration
  - Fast-track ("Me-Too")
  - Non-fast-track
- Amendments to Existing Registrations
  - New uses
  - Non-fast-track amendments
  - Fast-track amendments
- Other Types of Registrations
  - Experimental use permit
  - Special local need (Section 24(c))
  - Emergency exemption (Section 18)
  - Inert Petition

WHY ARE DATA NEEDED

- Purpose:
  - Identify product
  - Assess health and environmental risks
  - Ensure benefits (i.e., efficacy)
  - Make a regulatory decision with mitigation (if needed)

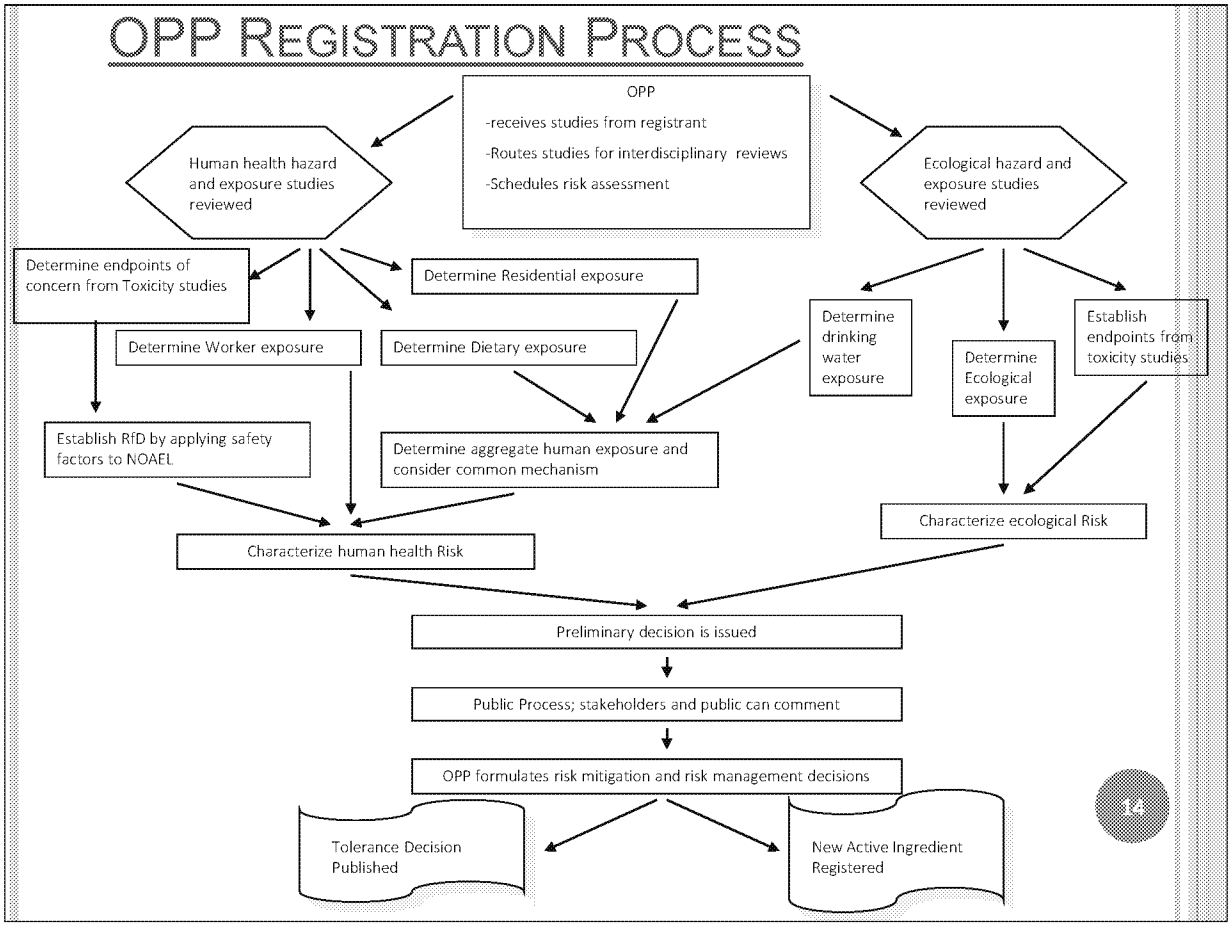
- Generic Data and Product-Specific Data

DATA REQUIREMENTS

- Data requirements depend on the proposed use(s):
  - More data required to register new food use pesticide than one with no food uses
  - Antimicrobials, biopesticides, and conventional pesticides each have different data requirements
- Up to 150 different studies may be required to register a pesticide, including:
  - Product Chemistry
  - Toxicology and Health Effects
  - Applicator and Post-Application Exposure
  - Residue Chemistry
  - Environmental Fate
  - Ecotoxicity
  - Efficacy

Fulfilling Data Requirements

- Data Generation
  - OCSPP Harmonized Testing Guidelines
  - Formatting Data
- Data Citation
  - Data Rights and Data Compensation Requirements
- Data Exemption
  - Formulator's Exemption


OPP REGISTRATION PROCESS
OPP
-receives studies from registrant
-Routes studies for interdisciplinary reviews
-Schedules risk assessment
Human health hazard and exposure studies reviewed
Ecological hazard and exposure studies reviewed
Determine endpoints of concern from Toxicity studies
Determine Residential exposure
Determine Worker exposure
Determine Dietary exposure
Determine drinking water exposure
Determine Ecological exposure
Establish endpoints from toxicity studies
Establish RfD by applying safety factors to NOAEL
Determine aggregate human exposure and consider common mechanism
Characterize ecological Risk
Characterize human health Risk
Preliminary decision is issued
Public Process; stakeholders and public can comment
OPP formulates risk mitigation and risk management decisions
Tolerance Decision Published
New Active Ingredient Registered
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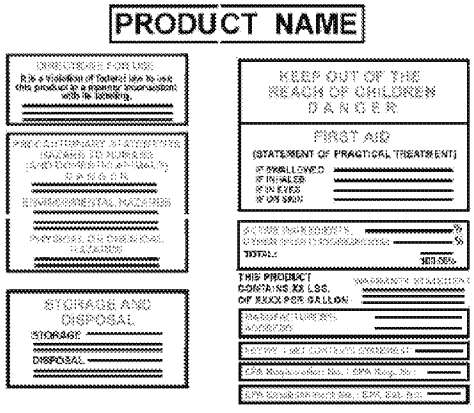
THE LABEL IS THE LAW



- EPA Registration Number
- Establishment Number
- Directions for Use
- Signal Word
- First Aid
- Ingredients Statement
- Precautionary Statements
- Hazards Statements
- Environmental Hazards
- Physical or Chemical Hazards
- Storage and Disposal
- Warranty Statement
- Net Contents

Labeling requirements are product-specific, and are informed by the data.

Pesticide Labeling

- When a new product registration application is submitted, it must include a draft/proposed label.
- OPP reviews the label in conjunction with the submitted data to ensure that every statement on the label is reflective of and supported by the data.
- The label must be accurate – it must make sense and be clear to the user – and it must contain language that is enforceable.

Additional Information Resources for Labeling

- **Label Review Manual.**
  - Available at: http://www.epa.gov/oppfead1/labeling/lrm/
- **Pesticide Product Labels Webpage.**
  - Available at: http://www.epa.gov/pesticides/regulating/labels/product-labels.htm
- **Pesticide Registration (PR) Notices**.
  - Available at: http://www.epa.gov/PR_Notices/index.htm

Transparency and Public Process

- Transparency and public participation are important aspects of EPA's Pesticide Program.
- The public can review and comment on the risk assessments and proposed registration decisions for certain pesticide registration actions.
- Public input informs the risk assessment and risk management processes associated with registration.

Public Participation Process for Registration Actions

- Federal pesticide law requires the opportunity for public participation in certain parts of the pesticide registration process.
- In 2009, EPA began implementing a public participation process for certain registration actions.
- The Agency solicits public participation for the following types of product applications:
  - new active ingredients;
  - first food use;
  - first outdoor use;
  - first residential use; and
  - other actions of significant interest.

Public Participation Process for Registration Actions

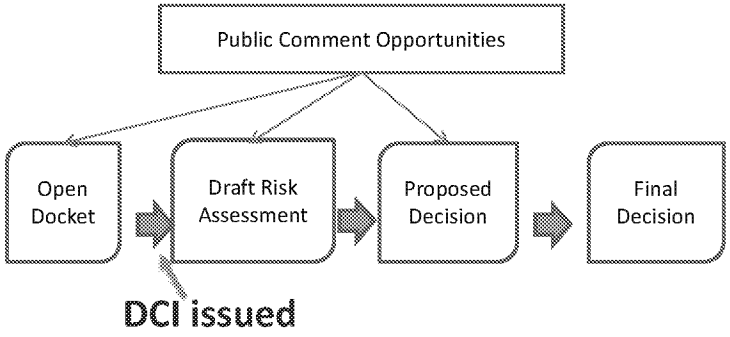
- Publish in the Federal Register a Notice of Receipt and Notice of Filing when an application and/or tolerance petition is received.
- This notice will open a public docket and provide an initial 30-day comment period followed by another 30-day comment period when the risk assessments and proposed decision have been completed and added to the docket.
- After the comment period closes, analyze the comments received, prepare a response-to-comment document and revise assessments and related decision documents, as needed.
- Make a final decision on the registration. Supporting documents will be placed in the public docket.
- Publish a Notice of Issuance in the Federal Register for the final decision.

What is Registration Review?

- As part of its 1996 amendments to FIFRA, FQPA created the registration review program
  - Requires EPA to review each pesticide's registration every 15 years (40 CFR Part 155.40)
- Implementation of the program began in 2007 (prior to 2007, a different program, reregistration, informed review of existing pesticides)
  - Data call-ins (DCIs) issued for any data needed for registration review
  - Transparent process with opportunities for stakeholder input
  - Risks assessed, mitigation determined if needed
  - Decisions issued
- By October 1, 2022 EPA must complete registration review for pesticides registered in 2007 and earlier (AD has 139 cases to complete)

REGISTRATION REVIEW

- Periodic review of all registered pesticides -- occurs every 15 years
- Preliminary Work Plan (public docket opening)
- Focus Meetings
- Final Work Plan
- Issue Data Call-In (DCI)
- Draft Risk Assessment
- Proposed Interim Decision or Proposed Final Decision
- Interim Decision or *Final Decision
- Risk mitigation/label changes



*The final decision may be preceded by an interim decision. The conclusion of a particular registration review occurs once a final decision is issued.

DATA CALL-INS (DCI)

- OPP has authority under FIFRA to require generation and submission of needed data or information
- DCIs issued for any data needed to address concerns, such as those pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide
- Generic (GDCI) –
  - Data are specific to the active ingredient
  - Utilized under registration review program to address data gaps/uncertainties
- Product-Specific (PDCI) –
  - Data are specific to and generated on each product
  - Triggered when new/updated scientific understanding warrants reconsidering registered products and their label claims
    - E.g., updating an efficacy testing guideline may trigger a need for a PDCI on affected products

Example Registration Review Timeline

Activities	Estimated Month/Year
Opening the Docket	
Open Docket and 60-Day Public Comment Period for Preliminary Work Plan (PWP)	Start
Close Public Comment Period	2 months after start
Case Development	
Issue Final Work Plan (FWP)	6 months after start
Issue Data Call-In (DCI)	6-12 months after FWP
Data Submission	1-3 years after DCI
Open 30/60-Day Public Comment Period for Draft Risk Assessments (DRA)	1 year after data submission
Close Public Comment Period	2 months after DRA
Registration Review Proposed Decision	
Open 60-Day Public Comment Period for Proposed Registration Review Decision (PID)	6 months after DRA
Close Public Comment Period	2 months after PID
Final Decision	6 months after PID
Estimated Total (years)	5 - 7 years

Alternatives and benefits

- The registration standard under FIFRA requires balancing of risks and benefits
  - Note: The safety standard under the FFDCA is a risk-only standard and does not allow consideration of benefits. Benefits information cannot be used to allow use on food that has been determined to be unsafe.

- Where risks to human health or the environment are identified, EPA assesses benefits of pesticide use to determine whether benefits outweigh risks and whether any risk mitigation is necessary

WHERE CAN I FIND.....?

- Information on EPA's registration of antimicrobial pesticides: https://www.epa.gov/pesticide-registration/antimicrobial-pesticide-registration
- Information on EPA's reevaluation of pesticides: www.epa.gov/pesticide-reevaluation
- The registration review schedule: www.epa.gov/pesticide-reevaluation/registration-review-schedules
- Pesticide Chemical Search: iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1
- EPA pesticide label searches: https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1
- Contacts in the OPP's Antimicrobials Division: https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division

QUESTIONS?